

EU Alliance's Submission to the UN's High-Level Panel on Access to Medicines

Organisations who endorse this submission: STOPAIDS, Health Action International, Health Gap (Global Access Project), Wemos, UAEM Europe, Youth Stop AIDS, ACTSA, Health Poverty Action, Commons Network, Grupo de Ativistas em Tratamentos, Coalition Plus, Salud Por Derecho, Global Health Advocates, Restless Development, T1International, Aids Orphan, Declaration de Berne, Medicines in Europe Forum, European Public Health Alliance, PRAKSIS, EKPIZO, VDPP, EATG.

SECTION 1: ABSTRACT

We, representatives of civil society—consumer, patient and public/global health organisations—call for the creation of a research and development (R&D) framework that is driven by global public health needs and delivers quality medicines that are universally accessible and affordable.

Due to the urgency needed to resolve the failures of our current system for researching and developing medicines in order to avoid loss of life we propose a phased approach to reform, set out below.

- Remedy the most acute problems with our current market-driven pharmaceutical model by:
 - Securing affordable prices through using effective price control mechanisms and strengthening the use of full TRIPS flexibilities in all countries
 - Putting an end to pharmaceutical monopolies by promoting generic and biosimilar competition and their usage; increasing scrutiny of anti-competitive practices by the pharmaceutical industry and strengthening the work and use of the Medicines Patent Pool

- Demanding more stringent proof of therapeutic advance before authorizing new medicines into the market
- Implement full transparency of pharmaceutical R&D and medicine price setting, by:
 - Promoting open access to all research data
 - Fully disclosing and tracking public and private funding for pharmaceutical R&D
 - Establishing a publicly accessible database where health systems publish the price of medicines that they negotiate
- Promote a new global biomedical R&D agreement which would include:
 - Committing increased public funds to support a needs-driven approach to pharmaceutical R&D that delivers affordable health technologies while ensuring both transparency and public return for public investment.
 - Funding new R&D initiatives which delink the real costs of R&D from the end price
 - Creating a global observatory for R&D to track spending, identify areas of health need and encourage coordinated research efforts into priority areas through open-source research to deliver safe and effective medicines that offer real therapeutic progress.

Introduction (outlining the problem)

In Europe and worldwide, the price of new medicines is rising year on year, especially where there is no therapeutic alternative. As a result, treatment for life-threatening infections and diseases, like HIV/AIDS, cancer and hepatitis C, are increasingly unaffordable for both individuals and national health systems. This is the result of an ineffective and costly research and development (R&D) system that rewards new medicines with fixed-term monopolies (patents) and encourages unaffordable price setting. This patent-based system grants pharmaceutical companies monopolies, which allow them to charge exorbitant prices for health technologies totally unconnected to the cost of developing them.¹ Urgent measures must be taken to ensure that people can afford the medicines they need.

High prices are often understood and accepted as a necessary evil of the patenting system, required as a reimbursement strategy and a way of financing future innovation. However, this necessary evil must be brought into question if it is not encouraging innovation to meet the world's most pressing health needs. The reality is that currently, biomedical innovation takes place within a framework that prioritises R&D not according to public health need but according to the profit that stands to be made. This leads to skewed priorities that have life-threatening consequences². For example in the last 40 years we've only produced 2 new treatments for tuberculosis, a disease that kills over 1.5 million people a year, but we've produced 14 new medicines for hay fever within the same time period.³ Moreover, neglected tropical diseases, despite representing 14% of the global burden of disease, only receive 1.3% of global research funding⁴.

The extent to which patents incentivise innovation also requires some analysis. With profit as the goal, pharmaceutical companies are more inclined to make subtle changes to existing compounds and remarket them under a new brand name. As a result our medical market is flooded with "me-too" drugs, which draws into question

¹ ACCESS DENIED: Report of the Inquiry of the All Party Parliamentary Group on HIV and AIDS into access to medicines in the developing world December 2014 <http://impactaids.co.uk/wp-content/uploads/ACCESS-DENIED-APPG-Report-1.12.14.pdf>

² Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests? Council of Europe, [Resolution 2071 \(2015\)](#), September 2015

³ Debate at the UK Parliament (Commons), Mr Peter Hain (Neath) (Lab), 8 July 2014: http://www.publications.parliament.uk/pa/cm201415/cmhansrd/cm140708/halltext/140708h0002.htm?dm_i=6N7,2M284,GPCQXA,9LHU3,1

⁴ von Philipsborn P, Steinbeis F, Bender ME, Tinnemann P. Poverty-related and neglected diseases: an economic and epidemiological data analysis of poverty relatedness and neglect in research and development. *Glob Health Action* [Internet]. 2015;382(25818):7. Available from: <http://www.sciencedirect.com/science/article/pii/S0140673613621686>

the logic behind patents as a reward for ‘novel’ ideas.⁵ For example, the independent Drug Bulletin Prescrire has assessed the added therapeutic value of 1345 drugs between 2000 and 2013 and found that only 7% offered ‘a real advantage’ when compared to drugs already on the market.⁶

Inefficiency is also driven by the secrecy and lack of transparency within our current R&D model which results in research being duplicated or high transaction costs for getting access to previous clinical trial data under data exclusivity protection.⁷ A lack of transparency also makes it hard for health systems to negotiate prices since they don’t have access to data on the true costs of R&D. Lastly, the lack of transparency on safety and efficacy data, and the fact that many companies selectively publish their clinical trial data creates a dangerous situation for patients.⁸

These examples show that clearly our current R&D model is not delivering the health technologies that are most needed and what they are delivering is often lacking in added therapeutic value compared to what is already on the market or is so heavily over-priced that it is unaffordable for individuals and health systems. The current biomedical R&D model is no longer just failing the poor—it is progressively failing us all.

1) Impact on remedying policy incoherence

Our current R&D model rests on the fundamental incoherence between the right to health and the monopoly interests of IP right holders. These monopoly interests are born from a system where the market, rather than public health need, is the driving force of health technology production. This must be remedied since the market is a moral-less, inhuman force which is entirely inappropriate and unsuitable for

⁵ T. Fojo T et al. “Unintended consequences of expensive cancer therapeutics – the pursuit of marginal indications and a me-too mentality that stifles innovation and creativity” JAMA Otolaryngology Head and Neck Surgery (2014).

⁶ Prescrire (2014); 34 (364):132-136 ‘New drugs and indications in 2013: little real progress but regulatory authorities take some positive steps’ available at <http://www.ncbi.nlm.nih.gov/pubmed/24860905>

⁷ World Health Organisation (2006) Briefing note: Access to medicines, DATA EXCLUSIVITY AND OTHER “TRIPS-PLUS” MEASURES http://www.searo.who.int/entity/intellectual_property/data-exclusivity-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf

⁸ BMJ (2013) Non-publication of large randomized clinical trials: cross sectional analysis 2013; 347 doi: <http://dx.doi.org/10.1136/bmj.f6104>

delivering health outcomes and protecting the human right to affordable and appropriate health care.

The R&D reforms we propose would remedy this incoherence by challenging the monopoly interests of right holders in the short term whilst encouraging the development of an R&D agreement that would replace market drivers entirely with a sustainable, publically-driven, financed and coordinated framework.

By enforcing transparency of R&D investment, IP right holders would have to divulge the breakdown of public and private investment for a health technology including the financial, human resource and tax inputs in order to justify the price. This, coupled with a database of what all countries pay for medicines would give the public the opportunity to hold the industry to account and challenge them over their exorbitant pricing practices. In this way the public and, with it, public health need is able to temper the driving force of the market and they are empowered to challenge decisions over pricing and R&D investment with evidence-based arguments.

Access to this data is understood as freedom of information which is an extension of freedom of speech, a fundamental human right. Under the current model, if the pharmaceutical industry are going to be responsible for the delivery of health needs - which should in fact be the obligation of the state - then freedom of information must be applicable to this sector on a global scale to safeguard the human rights agenda.⁹ The need for increased transparency and how it relates to human rights and public health is set out very clearly within MSF, KEI, Transparency International and Treatment Action Campaign's submission on transparency.

Other short term solutions to this policy incoherence are to address the impact that monopolies have on affordability by promoting the use of generic and biosimilar competition. This would require the reinvigoration and active encouragement of all countries to fully implement TRIPS flexibilities. Evidence has shown, as in the case of Thailand in 2007¹⁰, that to do this effectively there also needs to be legal sanctions for pharmaceutical companies that use coercive methods to try and dissuade countries from using TRIPS flexibilities to protect public health. To effectively

⁹ Mazhar Siraj (2010). "Exclusion of Private Sector from Freedom of Information Laws: Implications from a Human Rights Perspective" (PDF). *Journal of Alternative Perspectives on Social Sciences* 2 (1): 211 & 223.

¹⁰ Alcorn, K (2007) "Abbott to withhold new drugs from Thailand in retaliation for Kaletra compulsory license" <http://www.aidsmap.com/Abbott-to-withhold-new-drugs-from-Thailand-in-retaliation-for-iKaletra-compulsory-license/page/1426590/>

address the issue of monopolies would also call for the strengthening of the licensing agreements within the Medicines Patent Pool to ensure that a larger number of countries were included within the licenses and that restrictions that limit the possibility for generic producers to still be independent players on the global pharmaceutical market are lifted. International institutions would also need to do more to put pressure on pharmaceutical companies to share their patents through the pool to improve access and allow for additional research to be carried out.

The longer term solution to encourage inventors to meet public health needs is to entirely replace the market incentive to produce a new health technology with financial compensation that is sourced and managed by the public in the form of push and pull funding through a global observatory. In the R&D agreement we propose all health technologies for all health conditions would be exempt from IP protections in international, regional, bilateral, and national law as outlined in Brook Baker's submission on IP reform. All research data would also be open-source allowing for future innovations to build on previous progress to avoid duplication of efforts which would improve innovation efficiency.¹¹ Funding would only be available for 'needed' health technologies and, with no patent-monopolies, generic competition would drive prices down. This means we would be getting the right health technologies, at the highest possible standard and the lowest possible price.

2) Impact on public health

The R&D reforms we propose would be based on the principles of equity, openness and affordability, and devoted to meeting health needs around the world having a hugely positive impact on public health.

First and foremost, it would produce the medicines that we need since the public would have a role in holding the industry to account over their investment priorities as well as driving the agenda. This would mean that R&D investment was targeted to the areas of greatest therapeutic value, that would make the biggest difference to people's lives.

¹¹ Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (2012) "*Research and Development to meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*" http://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1

Secondly, the prices for health technologies would be made affordable to everyone and would be considered a public good by the non-enforcement of TRIPS on health technologies. This would, for the first time in history, create equitable access to health technologies and ensure that one's ability to access these technologies wouldn't rest on which country they were born in or on their bank balance.

Thirdly, by having a globally coordinated R&D observatory that ensured complete transparency we would greatly improve the efficiency of R&D and ensure that the health technologies produced offered the highest level of therapeutic value. This observatory has been recommended as a necessary part of a binding R&D agreement by the Consultative Expert Working Group on Research and Development (CEWG).¹² The one we propose would build on this model, strengthening the requirement of member states to use the observatory to inform R&D priorities. This observatory is essential since our current understanding of what R&D is being done, where, how and by whom is severely limited and this information is vital if we want to improve priority setting and the public health impact of biomedical R&D.¹³

The responsibilities of an observatory would include monitoring financial flows and how they correspond to pipelines helping policy makers set priorities according to health needs. It would also publish all clinical trial and research data meaning researchers could easily identify projects that were similar to their own allowing them to build on existing work to produce more effective products.¹⁴ In this way, we would improve innovation through enhanced transparency of existing R&D efforts helping us to respond quickly to global health challenges such as antimicrobial resistance and the emergence of (new) infectious diseases such as zika, ebola, MDR-TB. Consensus over the logic of sharing data in drug development is building, reflected in the WHO statement in September 2015 on 'Developing global norms for sharing

¹²Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (2012) "Research and Development to meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination" http://www.who.int/phi/CEWG_Report_5_April_2012.pdf?ua=1

¹³ Røttingen, J et al (2013) "Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?" Volume 382, No. 9900, p1286–1307, 12 October 2013 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61046-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61046-6/fulltext)

¹⁴ Røttingen, J et al (2013) "Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?" Volume 382, No. 9900, p1286–1307, 12 October 2013 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61046-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61046-6/fulltext)

data and results during public health emergencies¹⁵ which many global health bodies are supporting.¹⁶

Securing access to affordable and appropriate medicines is also essential for us to meet SDG 3 on health which already asserts 'access to affordable essential medicines and vaccines' within its targets. It also includes targets to end TB, HIV, malaria, combat hepatitis C and neglected tropical diseases as well as cutting non-communicable diseases by a third. For all these conditions, medicines are an essential part of effective treatment but for infectious diseases like HIV treatment is also a necessary element of prevention and crucial to bringing down infection rates. However infection rates and deaths will rise if new ARVs continue to cost between \$3000 and \$28,000 per person per year in middle income countries.¹⁷

It is also necessary in the realisation of universal health coverage (UHC). Countries will only be able to realise UHC¹⁸ - which includes access to safe, effective, quality and affordable essential medicines and vaccines for all - if we increase R&D into unmet health needs and ensure that medicines are affordable otherwise stock-outs and rationing will continue.

3) Impact on human rights

'It is health that is real wealth and not piece of gold and silver'. Mahatma Gandhi

Health is considered our most basic and essential asset.¹⁹ A precursor to our ability to lead fulfilling lives and participate meaningfully as a member of a family and a community. The right to health includes access to timely, acceptable, and affordable

¹⁵ World Health Organisation (2015) *Developing global norms for sharing data and results during public health emergencies*

http://www.who.int/medicines/ebola-treatment/blueprint_phe_data-share-results/en/

¹⁶ Wellcome Trust (10/022016) *Sharing data during Zika and other global health emergencies*

<http://blog.wellcome.ac.uk/2016/02/10/sharing-data-during-zika-and-other-global-health-emergencies/>

¹⁷ World Health Organisation (2014) *Increasing access to HIV treatment in middle-income countries: Key data on prices, regulatory status, tariffs and the intellectual property situation*

http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf, p16

¹⁸ Røttingen, J et al (2013) "Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?" Volume 382, No. 9900, p1286–1307, 12 October 2013 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61046-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61046-6/fulltext)

¹⁹ Office of the United Nations High Commissioner for Human Rights, "The Right to Health" *Fact Sheet No.31* <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>

health care of appropriate quality²⁰ and it is the duty of states to ensure that this right is realised. Replacing market incentives to produce medicines with public-health incentives will allow duty bearers to meet their human rights commitment.

States must also guarantee the right to health, like all human rights, in a non-discriminatory manner where no attribute including property, birth or status can affect one's ability to fulfill their rights. Our current way of doing medical R&D which creates high prices makes it very difficult for states to meet this obligation.. Expensive health technologies result in individuals and health systems having to reject needed technologies leading to rationing. For example direct-acting antivirals for the treatment of hepatitis C have created a never-seen situation in high-income countries: due to astronomic prices, public healthcare systems and insurance companies have restricted access to those treatments.²¹

The office of the United Nations High Commissioner on Human Rights states that "Human rights are interdependent, indivisible and interrelated. This means that violating the right to health may often impair the enjoyment of other human rights, such as the rights to education or work, and vice versa."²² Good health is required to be able to attend school and go to work but when high prices of medicines lead to scarcity patients are forced into fronting the extra capital to meet their health needs or simply going without. The World Health Organisation estimates that this leads to an additional 100 million people every year being pushed under the poverty line and leads to unnecessary deaths.²³ Bad health can lead to increased discrimination and stigma and this can exacerbate inequality undermining one of the overarching principles of human rights which is to promote equality.

A transparent, public-health driven approach to R&D means that we will not only have a positive impact on the human right to health but also the right to access to

²⁰ Office of the United Nations High Commissioner for Human Rights, "The Right to Health" *Fact Sheet No.31* <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>

²¹ Boseley, S (16/12/2015) *Hepatitis C drug delayed by NHS due to high cost* <http://www.theguardian.com/society/2015/jan/16/sofosbuvir-hepatitis-c-drug-nhs> ; Hammerstein, D (2015) High priced hepatitis C treatments spark massive public outcry and political debate in Spain <http://tacd-ip.org/archives/1270>

²² Office of the United Nations High Commissioner for Human Rights, "The Right to Health" *Fact Sheet No.31* <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>

²³ World Health Organisation (2015) *Health and human rights* <http://www.who.int/mediacentre/factsheets/fs323/en/>

information, to freedom from discrimination, to participation and the right to benefit from the scientific progress and its applications.

4) Implementation

The issue of irresponsible R&D and unaffordable medicine is a global problem which requires a global solution. Instead of scattered efforts, ultimately a global agreement is needed in order to guarantee equity in access to essential medicines and vaccines for all.

In the shorter term governments need to regulate the pharmaceutical industry and make the transparency of all R&D data a legal requirement. This will discourage evergreening and improve research efficiency. Most critically it will allow governments to negotiate appropriate costs for health technologies that are reflective of R&D investment from public and private sources. Governments must also make full use of TRIPS flexibilities to encourage generic production and the UN HLP must monitor the behaviour of pharmaceutical companies in reaction to the use of TRIPS flexibilities and reprimand them appropriately. Governments must also encourage the uptake of generic medicines by health practitioners to cut health technology procurement costs and apply a stricter level of scrutiny to the anti-competitive actions of pharmaceutical companies including the outlawing of TRIPS plus provisions in free trade agreements.

The longer term solution of a global agreement on R&D would require financial commitments from governments taking into account factors such as each nation's level of development, size of economy and capacity to pay; through a variety of means, including taxes and contributions in kind. We feel it is very important that the burden for R&D is shared as is the responsibility to set priorities.

Governmental funds to biomedical R&D will ensure that publicly-funded labs and independent entities develop healthcare products to face real global health challenges, instead of profit-driven R&D. Funds would go to award grants to independent entities and inducement prizes. In this way government's health-related expenditure would be shifted from paying high prices for medicines to upfront investment in R&D and the savings governments would make from cheaper health technologies could be reinvested back into needs-driven R&D. The coordination of

this fund would be managed multilaterally through a fully-transparent global observatory that could sit within a UN department where member states, informed by their public, would set R&D priorities through democratic means based on a needs-based criteria.²⁴

For grant and prize recipients their funding would be distributed on condition that products would be free from patent protection, since the funding would, effectively, buy-out the IP. Without patent monopolies all products are open to generic competition which is proven to be the most effective and sustainable way of keeping drug prices down. The unanimous non-application of IP to health technologies would require a shift in the terms of (TRIPS), as outlined in Brook Baker's submission on 'IP reform' and use these alternative cash incentives as a replacement for patents.

We have already seen examples of how push funding has been used successfully for example since its inception in 2003, the Drugs for Neglected Diseases Initiative (DNDi) which is a PDP has delivered six treatments including two fixed-dose anti-malarials, a drug for late-stage sleeping sickness, a combination therapy for visceral leishmaniasis, a set of combination therapies for visceral leishmaniasis and a pediatric treatment for Chagas disease. We also have good models for pull funding such as Bernie Sander's proposed Medical Innovation Prize Fund. This Fund would replace monopolies with more than \$80 billion (0.55% of US GDP) in annual rewards for useful investments into R&D including interim research and development activities. The legislation would eliminate all monopolies on the sale of approved drugs and vaccines, encouraging generic competition which is expected to lower the cost of drugs by more than \$250 billion per year for the US domestic market, making a massive saving for health insurers, employers and patients.²⁵

The establishment of an R&D agreement would also require a significant political commitment from governments to shift the meaning behind why we produce medicines working toward a situation where medicines are considered a public good. To help build the rationale for this move, a cost-benefit analysis of current spending on R&D and drug procurement set against the savings that could be made through the R&D framework we propose, should be produced. The Lancet has already

²⁴ Røttingen, J et al (2013) "Mapping of available health research and development data: what's there, what's missing, and what role is there for a global observatory?" Volume 382, No. 9900, p1286–1307, 12 October 2013 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61046-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61046-6/fulltext)

²⁵ Knowledge Ecology International (2011) *The Medical Innovation Prize Fund*, http://keionline.org/sites/default/files/big_prize_fund_overview_26may2011_a4.pdf

asserted that although that costings for an observatory need to be researched ‘the costs of such work would be modest compared with the potentially beneficial ramification if R&D coordination is improved’.²⁶

The political commitment would also include a shift in the power dynamic between governments and industry which is likely to incur significant industry pushback. The UN High Level Panel should play a leading role in supporting this shift through the recommendations of the panel and ensure that substantial time and resources is invested in making equity in healthcare a global norm.

²⁶ Røttingen, J et al (2013) “Mapping of available health research and development data: what’s there, what’s missing, and what role is there for a global observatory?” Volume 382, No. 9900, p1286–1307, 12 October 2013 [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61046-6/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61046-6/fulltext)